Rebotix	Author	Document Number	Rev	Page
	Jeff Bua	PS-PR420205	C	1 of 27

Title: Product Specification: Rebotix Remanufactured EndoWrist REF 420205 Fenestrated Bipolar Forceps

PRODUCT SPECIFICATION

1. PURPOSE

The purpose of this Product Specification is to define the product specific requirements with sufficient detail to permit the design to be verified and validated.

2. SCOPE

This specification defines the requirements for Re-Manufactured EndoWrist REF 420205, Fenestrated Bipolar Forceps, Rebotix Drawing PR420205.

3. DEVICE DESCRIPTION

General Description that applies to all models of EndoWrists

The subject device(s) consist of a family of endoscopic instruments with either grasping or cutting end effectors to be used with the Intuitive Surgical da Vinci Endoscopic Instrument Control System. These instruments attach to the instrument manipulator arms on the Intuitive Surgical Endoscopic Instrument Control System. The instruments are re-usable (for a limited number of uses), are provided non-sterile, and must be cleaned and sterilized before used (pre-vacuum autoclave). The instruments are programmed for a limited number of uses to ensure reliability and consistent performance.

The instruments attach to disposable, sterile adaptor on the manipulator arm of the Endoscopic Instrument Control System to provide a barrier between the (sterile) instrument and the (non-sterile) manipulator arm. This allows instruments to be interchangeable during a procedure, without compromising the sterile barrier. When attached to the manipulator, the instrument is inserted through a cannula mounted to the manipulator.

All instruments have articulations at the distal end that are controlled by the surgeon. The instrument is the "wrist" of the system and provides four (4) degrees of freedom (wrist yaw, wrist pitch, rotation and grip). These instruments share similar architecture, materials, and manufacturing processes. The primary difference between the instruments is the tip end effector also known as the "tool end".

Re-Manufactured EndoWrist REF 420205, Fenestrated Bipolar Forceps Description

The Re-Manufactured EndoWrist Fenestrated Bipolar Forceps Instrument is a multiple-use endoscopic instrument to be used in conjunction with the Intuitive Surgical Endoscopic Instrument Control System. Refer to Figure 1 for an illustration of the instrument.

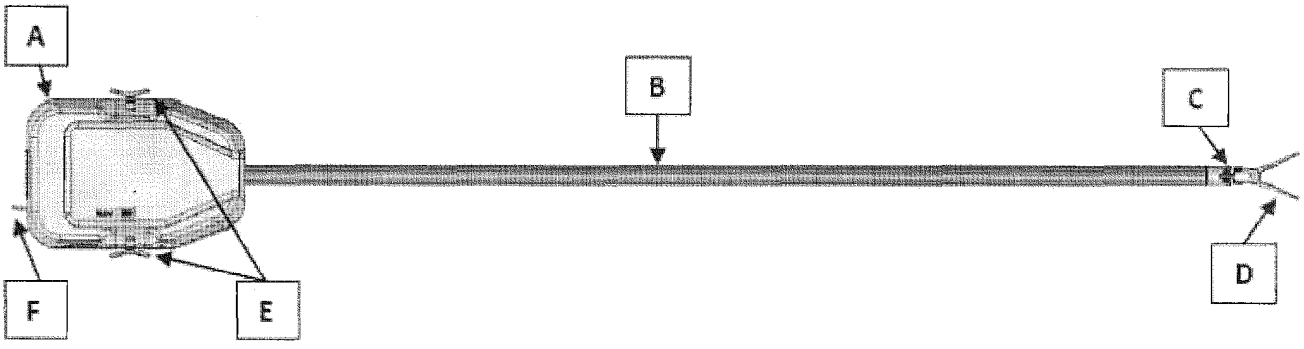

Figure 1

A. Back end housing with release levers used to remove instrument from the sterile adapter of the Intuitive Surgical Endoscopic Instrument Control System.
B. Insulated Shaft
C. Wrist
D. Tool End (distal end of Instrument sometimes referred to as end effector)
E. Release Levers
F. Bipolar Pins

The Rebotix Re-Manufactured EndoWrist REF 420205 is identical to the OEM version with the exception of the following:

Addition of a PCB assembly internal to the device to extend the uses to an addition 11 uses as displayed on the host system.

The Tool End is polished.

3.1 INTENDED USE

General Intended Use that applies to all models of EndoWrists

The Surgical Endoscopic Instruments including scissors, scalpels, forceps/pick-ups, needle drivers and electrocautery are intended for endoscopic manipulation of tissue, including: grasping, cutting, blunt and sharp dissection , approximation, ligation, electrocautery and suturing.

3.2 INTRAOPERATIVE USE

Rebotix Re-Manufactured EndoWrist Instruments shall be used only by a physician or medical personnel under the supervision of a physician.

4. ACRONYMS AND ABBREVIATIONS

The following acronyms and abbreviations are used within the text of this document.

[redacted]	[redacted]
IEC	International Electrotechnical Commission
OR	Operating Room
PCB	Printed Circuit Board
RF	Radio Frequency
IFU	Instructions for use
N/A	Not Applicable
PEMS	Programmable Electrical Medical Systems
DHF	Design History File
[redacted]	[redacted]
FPGA	Field Programmable Gate Array
CPLD	Complex Programmable Logic Device

Table 1 – Acronyms and Abbreviations

5. APPLICABLE [redacted] STANDARDS / CLASSIFICATIONS/ DOCUMENTATION

The following is a list of all documents and other sources of information referenced in this Product Specification.

Standard	Description
ANSI/AAMI/ES 60601-2-2:2009 [redacted] EN60601-2-2:2009	Medical electrical equipment, Part 2-2: Particular requirements for the safety of high frequency surgical equipment
[redacted]	[redacted]
[redacted] ANSI/AAMI/ES 60601-1:2005 EN60601-1:2005	Medical Electrical Equipment - General requirements for safety
ANSI/AAMI/IEC 62366:2013	Medical devices – Application of usability engineering to medical devices.
EN 980:2008	Symbols for use in the labeling of medical devices
EN ISO 13485:2012	Medical devices - Quality management systems [redacted]
EN ISO 14971:2012	Medical devices – Application of risk management to risk management to medical devices
EN60601-1-2:2007	Collateral standard: electromagnetic compatibility – requirements and tests.
ANSI / AAMI / ISO 10993-1:2009	Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing
[redacted] EN 50581:2012	[redacted] Technical documentation for the assessment of Electrical and Electronic Products with Respect to the Restriction of Hazardous Substances
Directive MDD 93/42/EEC Amended 2007/47/EC	European Commission's Medical Device Directive
EN1041:2008	Information supplied by the manufacturer of medical devices
EN62304:2006 / AC:2008	Medical Device Software – Software life cycle processes
DIN 58298: 2010-09	Medical Instruments - Materials, Finish and Testing

Table 2 – Applicable Standards

[redacted]

Rebotix shall be certified to ISO13485:2003.

A Risk/Hazard Analysis will be performed throughout the design process per ISO 14971:2012. The Risk/Hazard Analysis will be documented and filed as part of the design history file.

5.1 UNITED STATES (US)

us_safety_effectiveness

The Device shall be designed to meet the applicable electrical, mechanical, labeling and safety requirements of ANSI/AAMI/ES 60601-1:2005

[redacted]

[redacted]

5.4 OTHER

5.4.1 PROJECT DOCUMENTATION

Documents will be in standard Rebotix document format.
Risk Management shall be conducted per Rebotix's Risk Management procedure, SOP-1006

5.4.2 CATALOG NUMBER

The following table lists the Device's catalog number and description. Each device shall be labeled with an identifying lot code for traceability.

Catalog #	Comments
REF 420205	Re-Manufactured Fenestrated Bipolar Forceps

Table 4 - Catalog Number Reference

6. PHYSICAL CHARACTERISTICS

physical_characteristics_recovered_remaining_uses

In order for the device to be a candidate for Re-Manufacturing, it must have a minimum of 1 original remaining uses left on the memory device as recognized by the host unit. An original expired device, 10 uses, cannot be updated for extended life.

physical_characteristics_recovered_condition

In order for the device to be a candidate for Re-Manufacturing it must not have any visible defects. Including the following:

- unrepairable damage to the tool end
- frayed or broken cabling
- damage to insulated shaft

physical_characteristics_jaw_opening_angle

The jaw open angle from centerline of the device shall be 45° +/- 5° as controlled by the host system. See Figure 2

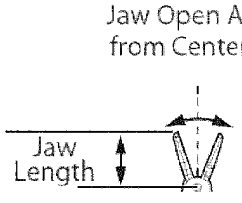

Figure 2

physical_characteristics_jaw_length

The jaw of the device shall be 21mm +/- 2mm in length. See Figure 2

physical_characteristics_compatible_RF generators

The device shall be compatible with the following RF generators (ESU), as indicated by the OEM:

- Valleylab Force Triad
- Valleylab FX
- Vallelab Force 2
- Erbe ICC 350
- ERBE VIO 300 D
- ConMed System 5000 (60-80005-001)
- Conmed Excalibur Plus PC (60-6290-120), (60-6250-001)
- Gyrus ACMI PK
- Gyrus ACMI SP
- Gyrus ACMI G400
- Megadyne Mega Power

7. PERFORMANCE CHARACTERISTICS

performance_characteristics_uses

The device shall be rated for 11 uses. One use is defined as a clinical use, scrub, cleaning and sterilization cycle.

performance_characteristics_instrument_type

The device shall be an Energy type EndoWrist.

performance_characteristics_energy_type

The device shall utilize Bipolar RF energy for localization and precise hemostasis and blunt tissue dissection.

performance_characteristics_RF_activations

The forceps of the device shall be rated for a minimum of 792 RF activations. RF activation is defined as the following:

- ESU – ConMed System 5000
- RF Mode – Macro Bipolar
- Power Setting – 90W
- Duration – 0.250 sec.

performance_characteristics_tool_exercise

The tool end of the device shall be rated for a minimum of 792 movements for the following directions.

- pitch up to maximum Host System Position
- pitch down to maximum Host System Position
- yaw right to maximum Host System Position
- yaw left to maximum Host System Position
- rotate clockwise to maximum Host System Position
- rotate counter-clockwise to maximum Host System Position

performance_characteristics_grip

The tool end of the device shall be rated for a minimum of 792 open / close movements for gripping during normal use.

During the life (1-792 grips) of the device, the gripping force shall meet the requirements of DIN 58298: 2010-09 section 5.4 (referencing Appendix C- for non-cutting instruments).

8. Safety Design Requirements

The following features are required for the safe operation of the device:

8.1 Biocompatibility

safety_biocompatibility

The patient contacting parts of the device shall be Biocompatible per the requirements of ANSI / AAMI / ISO 10993-1:2009, Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing. The following testing shall be performed to validate the Re-Manufacturing components and process:

- ISO MEM Elution
- ISO Maximization Sensitization Test
- ISO Acute Systemic Injection Test
- ASTM HemolysisTest
- ISO Intracutneous Reactivity Test

8.2 Electrical Safety

Note: OEM Maximum ESU Power Settings to stay below 610V Device Voltage Rating limit, see table below for list of approved ESU's, RF modes and power settings to use the device properly.

electrical_safety_rated_accessory_voltage

Rated Accessory Voltage Upeak = 610peak (Used for dielectric testing calculations)

[redacted]

[redacted]

9. ENVIRONMENTAL DESIGN REQUIREMENTS

The device must operate within all specifications under the environmental conditions listed below.

Ambient temperature range	10° to 40° C (50° to 104° F) **environmental_requirements_specs_operating_temp**
Relative humidity	30% to 75%, non-condensing **environmental_requirements_specs_relative_humidity**

Table 5 – Environmental Requirements/Intended condition for use

The device can be transported under the conditions listed below without causing damage to the unit.

Ambient temperature range	-40° to 70° C (-40° to 158° F) **environmental_requirements_specs_transport_temp**
Relative humidity	10% to 100%, non-condensing **environmental_requirements_specs_transport_rel_humidity**

Table 6 – Transport Conditions

The device can be stored under the conditions listed below without causing damage to the unit.

Ambient temperature range	10° to 30° C (50° to 86° F) **environmental_requirements_specs_storage_temp**
Relative humidity	10% to 75%, non-condensing **environmental_requirements_specs_storage_rel_humidity**

Table 7 – Storage Conditions

9.1 MECHANICAL DESIGN REQUIREMENTS

Refer to Figures 3 and 4 for the mechanical assembly drawing of the device.

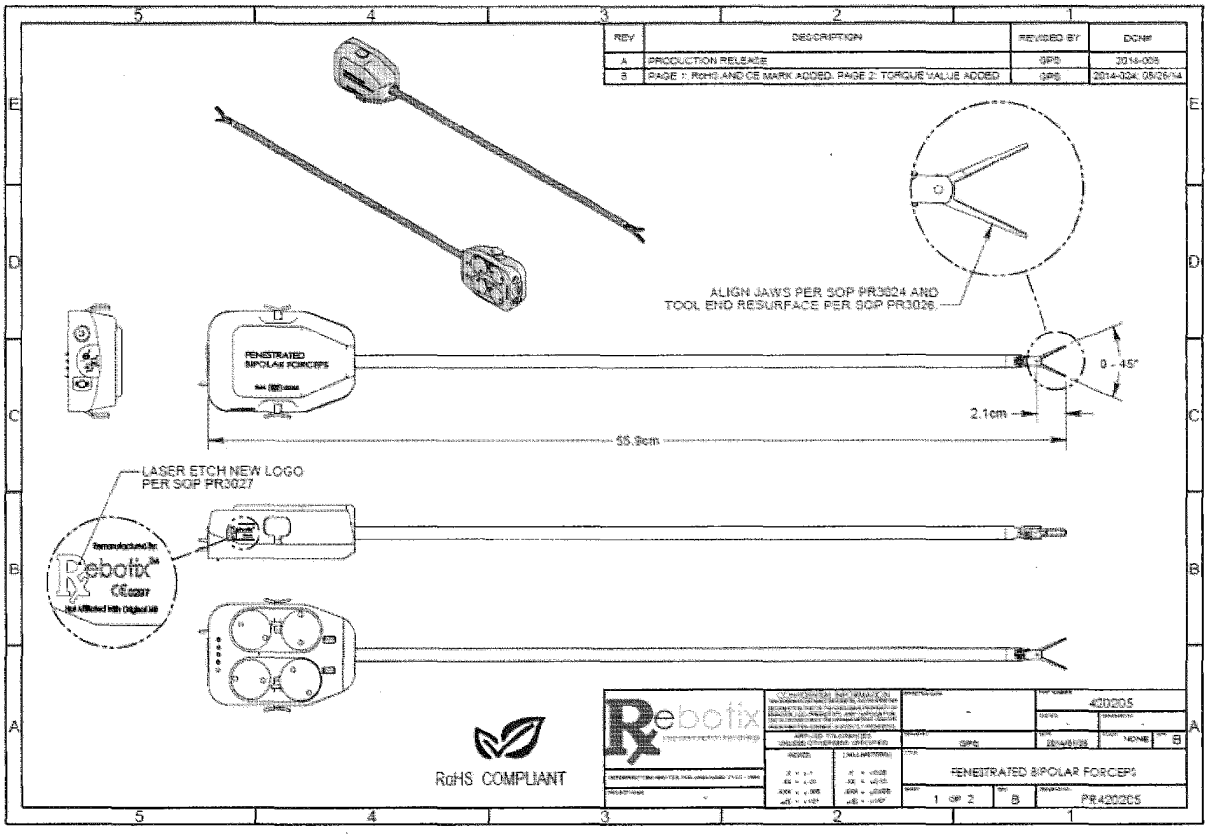
REV
DESCRIPTION
REVISED BY
DCN#
A
PRODUCTION RELEASE
GPS
2014-005
B
PAGE 1: ROHS AND CE MARK ADDED. PAGE 2: TORQUE VALUE ADDED
GPS
2014-024; 05/26/14
ALIGN JAWS PER SOP PR3024 AND
TOOL END RESURFACE PER SOP PR3026
FENESTRATED
BIPOLAR FORCEPS
0 - 45°
2.1cm
55.9cm
LASER ETCH NEW LOGO
PER SOP PR3027
RoHS COMPLIANT
Rebotix
420205
NONE
B
FENESTRATED BIPOLAR FORCEPS
1 OF 2
B
PR420205

Figure 3

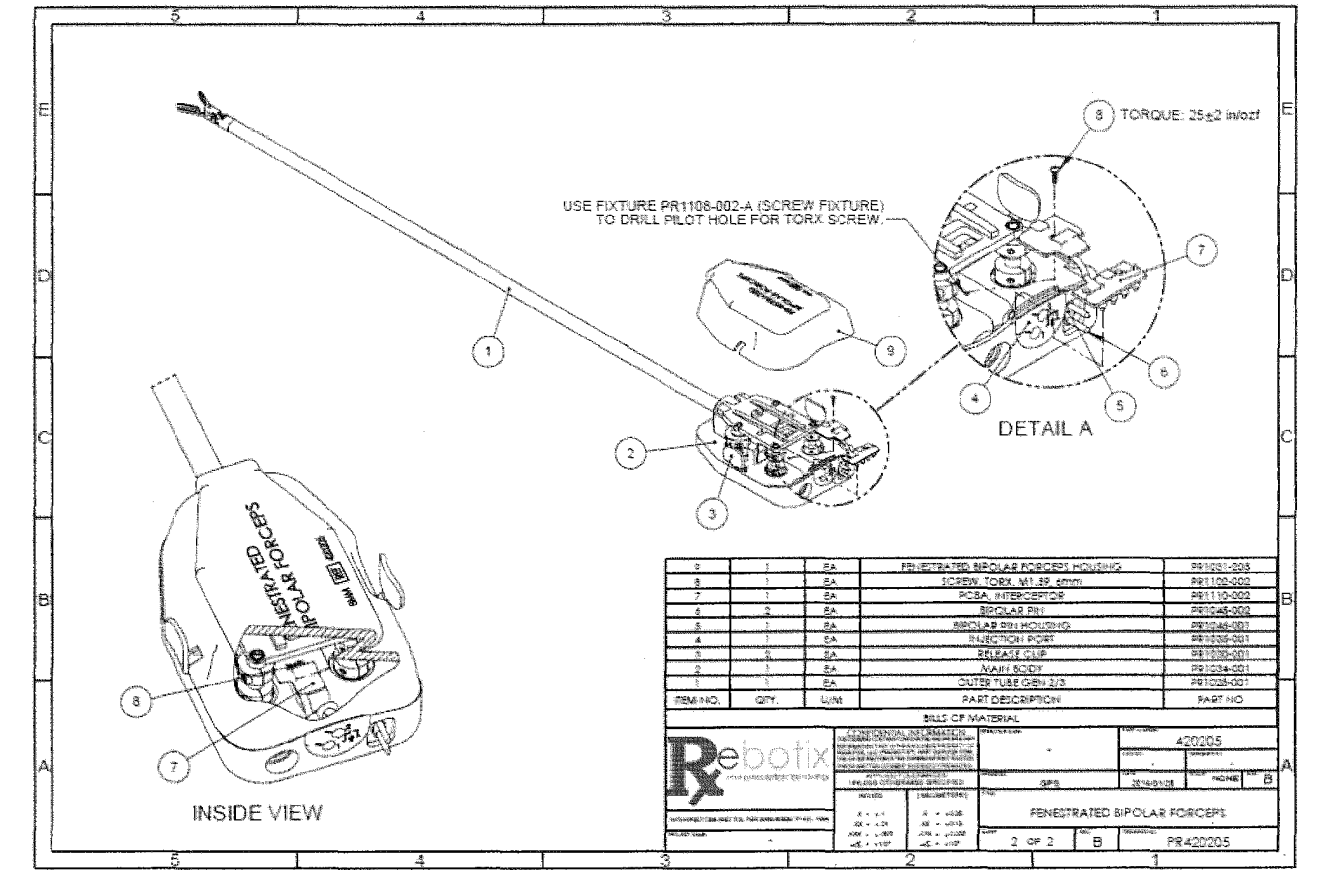

Figure 4

mechanical_physical_dimensions

Width shall be 6.5 cm +/- 2mm

Height shall be 3.49 cm +/- 2mm

Length shall be 55.9cm +/- 1cm

mechanical_physical_weight

Weight shall be less than 0.200 kg

mechanical_physical_shaft_diameter

The shaft of the device shall be 8.4mm +/- 0.1mm.

mechanical_physical_material

The device shall be composed of material that meets environmental, electrical and heat dissipation requirements. The material can be plastic or metal as long as all environmental, drop tests, and heat dissipation needs are met. All materials shall be of a flame retardant composition.

mechanical_physical_replacement_parts

All Re-Manufactured materials and parts must be substantially equivalent to the parts originally manufactured by the OEM in the device. All original OEM materials and parts are retained with the exception of the following parts replaced/added as part of the remanufacture process:

PCBA Interceptor, PR1110-002
PCB screw, PR1102-002
Housing etching compound, PR1142-002
Thread locker, PR1165-002
Bipolar Pin, PR1045-002

mechanical_degree of freedom_yaw

The jaws of the device shall move freely (without binding or slipping) in the Yaw directions (clockwise and counter-clockwise) to the tool clevis mechanical stops (See Figure 5) when the Yaw 1 and Yaw 2 wheels are rotated in both directions.

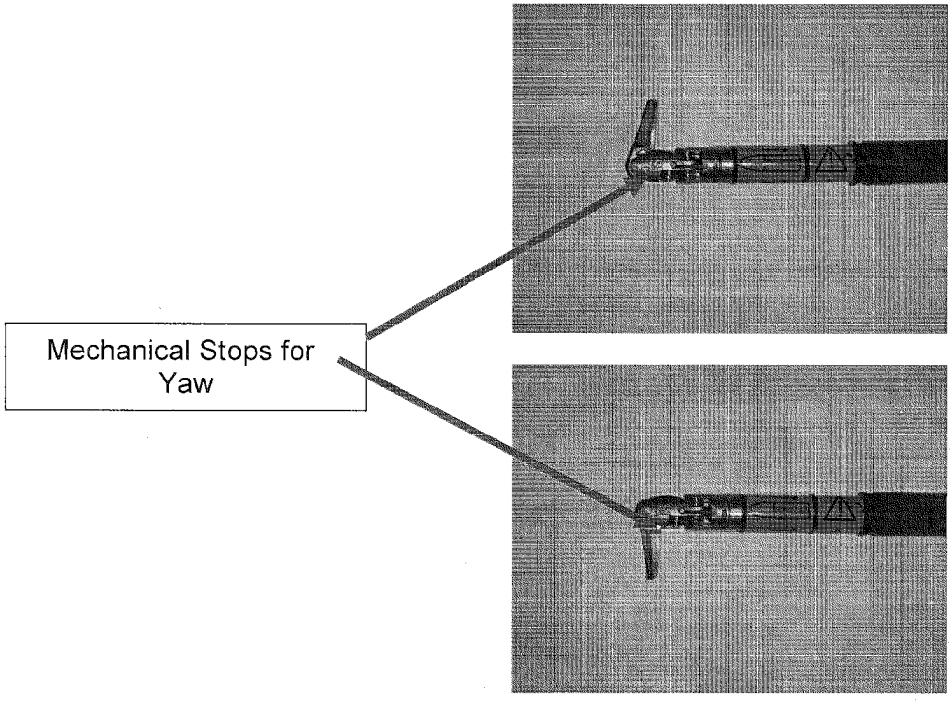

Figure 5

Note: Image represents wrist and tool clevis. Actual REF # may vary

The tool end of the device shall be at an angle of 0 +/- 5 degrees when the Yaw 1, Yaw 2 and Pitch 3 wheels of the device are locked in the home position. See Figure 7 for a definition of the home position for each of the wheels.

mechanical degree of freedom pitch

The Tool Clevis of the device shall move freely (without binding or slipping) in the Pitch directions (clockwise and counter-clockwise) to the wrist clevis mechanical stops (See Figure 6) when the Pitch 3 wheel is rotated in both directions.

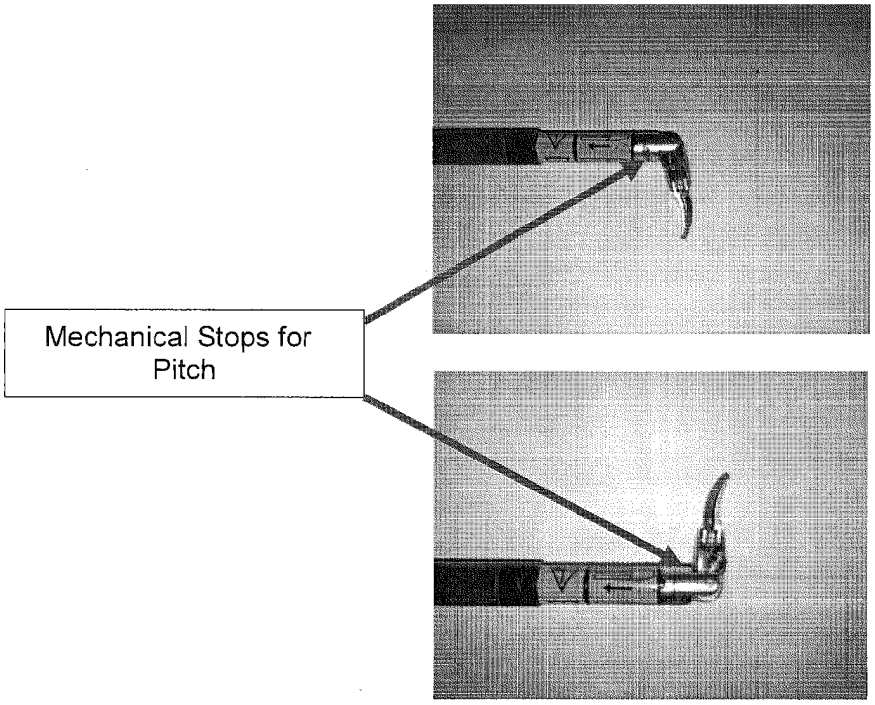

Figure 6

Note: Image represents wrist and tool clevis. Actual REF # may vary.

The Tool Clevis of the device shall be at an angle of 0 +/- 5 degrees when the Yaw 1, Yaw 2 and Pitch 3 wheels of the device are locked in the home position. See Figure 7 for a definition of the home position for each of the wheels.

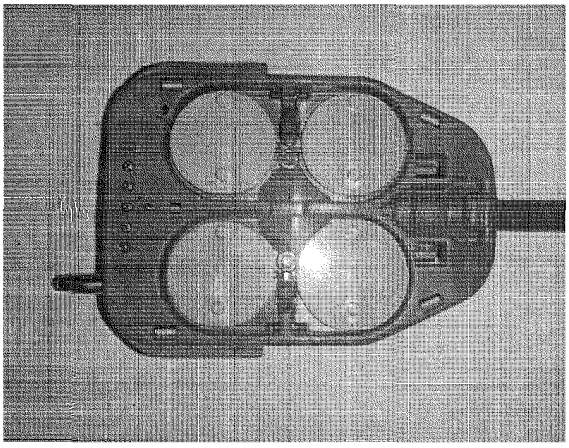

Figure 7

mechanical_degree_of_freedom_rotation

The device shall be capable of a rotational degree of freedom whereby the rotation wheel tab meets the full mechanical stop against the main body in both clockwise and counter-clockwise orientations.

mechanical_wheel_no_load_torque_yaw 1

The no load torque of the Yaw 1 wheel shall be calibrated to 2.9-7.8 in. oz f. of torque in the clockwise wheel rotation. The no load torque of the Yaw 1 wheel shall be calibrated to 2.0-5.0 in. oz f. of torque in the counter-clockwise wheel rotation. Refer to figure 8 for identification of the Yaw 1 wheel.

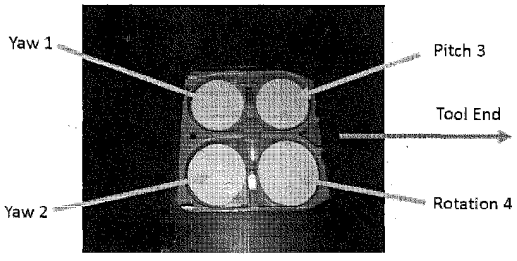

Figure 8

mechanical_wheel_no_load_torque_yaw_2

The no load torque of the Yaw 2 wheel shall be calibrated to 2.0 – 4.0 in. oz f. of torque in the clockwise wheel rotation. The no load torque of the Yaw 2 wheel shall be calibrated to 3.2 – 6.0 in. oz f. of torque in the counter-clockwise wheel rotation. Refer to figure 8 for identification of the Yaw 2 wheel.

mechanical_wheel_no_load_torque_pitch_3

The no load torque of the Pitch 3 wheel shall be calibrated to 3.2-7.5 in. oz f. of torque. (Clockwise and counterclockwise wheel rotation). Refer to figure 8 for identification of the Pitch 3 wheel.

mechanical_wheel_no_load_torque_rotation_4

The no load torque of the Rotation 4 wheel shall be calibrated to .25-2.0 in. oz f. of torque. (Clockwise and counterclockwise wheel rotation). Refer to figure 8 for identification of the Rotation 4 wheel.

mechanical_wheel_no_load_torque_wear_in

The no load torque of the Yaw 1, Yaw 2 and Pitch 3 wheels may loosen or tighten over to the extended life of the device to +/- 25% from the original calibrated values for Yaw 1, Yaw 2 and Pitch 3 in both clockwise and counter-clockwise directions.

mechanical_pcb_size

The interceptor PCB assembly shall be designed to mount into the housing without any mechanical interference with the operation of the Device.

mechanical_pcb_mounting

The Interceptor PCB assembly, Rebotix P/N PR1110-002, shall be securely mounted to the housing with a Torx M1.59 6mm screw torqued to 25 in. oz f. (+/- 2 in. oz. f)

mechanical_conformal_coating_material

The Interceptor PCB assembly, Rebotix P/N PR1110-002, shall be coated with the UV curable Loctite 5031 flowable sealant (PR1004-002).

mechanical_coating_UV_cure

The Interceptor PCB assembly, Rebotix P/N PR1110-002, shall be UV cured using the following: Equipment - Loctite 7411 UV Flood System, Curing time = 3.0 minutes

9.3 STERILIZATION

sterilization_autoclave

Withstand a minimum of 11 Pre-Vacuum autoclave sterilization cycles. The device shall be wrapped during the autoclave cycle. The autoclave setting shall be:

Parameter	Cycle
Temperature	270°-273°F or 132°-134°C
Exposure Time	Minimum 4 Minutes
Dry Time	20 Minutes

Table 8 – Autoclave Parameters

9.4 CLEANING PROCESS

ultrasonic_cleaner_parameters

Withstand a minimum of 11 Ultrasonic Cleaning cycles. The Ultrasonic Cleaner settings shall be:

Parameter	Cycle
Power	48watts/gallon (Minimum)
Frequency	38kHz (Minimum)
Temperature	113°F +/- 3.6°F or 45°C +/- 2°C
Time (Device Fully Immersed)	15minutes (Minimum)
Enzymatic Cleaning Solution	pH neutral Enzymatic Cleaning

	Solution

Table 9 – Ultrasonic Cleaner Parameters

Power - Ultrasonic power density shall be a minimum of 48 watts/gallon. (ultrasonic power output / internal tank volume).

cleaning process

The device shall be designed to withstand a minimum of 11 cleaning cycles after normal use. The instructions for cleaning are listed below:
Note: These cleaning instructions match the OEM's cleaning process instructions.

1. Scrub the entire outside of the Instrument using running water with a clean soft, nylon bristled brush, paying special attention to the Instrument tip. Move the Instrument wrist through its full range of motion while scrubbing.

2. Flush the main flush port for at least 20 seconds, using pressurized water at a minimum of 30 psi. While flushing the Instrument, hold the tip down and move the wrist through its full range of motion. Continue flushing until all of the water exiting the Instrument is clear.

A luer fitting attached to a filtered water line is recommended for connecting to the flush ports.

Flush ports are identified on the Instrument housing by the following symbol. 

3. Prime and Ultrasonically Clean the Instrument. Prime the Instrument using a syringe to inject a minimum of 15cc of enzymatic cleaning solution into the main flush port while immersing the Instrument tip in the ultrasonic bath. Immediately submerge the remainder of the Instrument.

Run the Instruments fully immersed in an ultrasonic bath filled with an enzymatic cleaning solution for at least 15 minutes.

An enzymatic cleaner specifically made to clean medical Instruments prepared according to the manufacturer's instructions is recommended. The enzymatic bath should be as close to 113°F or 45°C as allowed without exceeding the recommended temperature of the enzymatic detergent manufacturer.

For ultrasonic equipment to operate correctly, equipment must be properly maintained.

4. Repeat Flush. Remove the Instrument from the ultrasonic bath and repeat flush per Step 2.

Note: Repeat Step 3 (Prime and Ultrasonically Clean) and Step 4 (Flush) as necessary if water does not run clear.

5. Scrub the outside of the entire Instrument using running water with a clean soft, nylon bristled brush. Move the Instrument wrist through its full range of motion while scrubbing.

6. Rinse thoroughly the outside of the Instrument to remove any residual debris or cleaning agents. Specifically rinse into the area where the Instrument shaft enters the housing.

7. Dry the Instrument completely. Ensure that all water is emptied from the Instrument shaft and main flush port by vertically positioning the Instrument with tip up. Dry the outside of the Instrument with a lint-free cloth. Air may be blown through all flush ports to facilitate drying.

8. Lubricate the tip and wrist mechanism with a pH neutral, steam-permeable Instrument lubricant per the manufacturer's instructions. Proceed to sterilization.

9.5 Electrical Design Requirements

electrical_RoHS

The device shall be designed and components selected such that it meets the requirements for RoHS.

electrical_DC_resistance of RF_conductor

The total DC resistance of the RF conduction from each bipolar pin to the RF active tool end shall be 1.0 ohms or less.

electrical_DC_resistance of RF_conductors_to_Manipulation_Cables

The DC resistance of the RF conductors from each bipolar pin to Yaw 1, Yaw 2 and Pitch 3 Manipulation cables shall be greater than 10.0 MOhms. Refer to Figure 9 for measurement points.

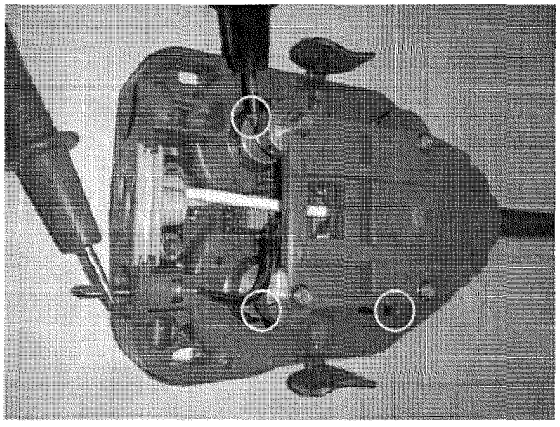

Figure 9

electrical_bipolar_RF_connector

The device shall contain a pair of bipolar pins to connect a bipolar RF cable to the rear of the device. Refer to figure 1.

electrical_bipolar_RF_connector_compatibility

The bipolar pins of the device shall be compatible with the following cables:

Bipolar Energy Activation Cable, Valleylab, Intuitive P/N 371498

Bipolar Energy Activation Cable, Erbe, Intuitive P/N 371499

Bipolar Energy Activation Cable, CONMED, Intuitive P/N 371500

Bipolar Energy Activation Cable, Gyrus, Intuitive P/N 370369

Bipolar Energy Activation Cable, Megadyne, Intuitive P/N 371483

electrical_memory_device

The Re-Manufacturing device shall harvest the original DS2505 memory device for use on the interceptor PCB assembly, Rebotix P/N PR1110-002.

electrical_conformally coated_pcb

The PCB assemblies internal to the device shall be conformally coated to handle the stresses of ultrasonic cleaning and autoclaving for a minimum of 11 life uses.

electrical_pcb_electrical_connections

The pin out from the device to the host system shall be.

Pin 1 – GND

Pin 2 – Data

Pin 3 - shorted to Pin 4.

Pin 5 – Not used.

electrical_communication_one_wire

The 1-wire® bus shall be used for device recognition by the host system.

electrical_pcb_power

The interceptor PCB assembly, Rebotix P/N PR1110-002, shall be parasitically powered by the 1-wire® bus in the DaVinci Surgical Robot

electrical_logic_device

The logic device used on the interceptor PCB assembly, Rebotix P/N PR1110-002, shall be Lattice P/N LCMXO2-1200ZE-1UWG25ITR50.

electrical_frequency

The frequency of the oscillator for the CPLD on the interceptor PCB assembly, Rebotix P/N PR1110-002 runs at 3.33 MHz +/- 5.5%. During normal operation the oscillator is shut down by way of the standby line to eliminate the dynamic power of the CPLD.

9.6 SOFTWARE DESIGN REQUIREMENTS

Refer to Figure 10 for the hardware-software architecture diagram.

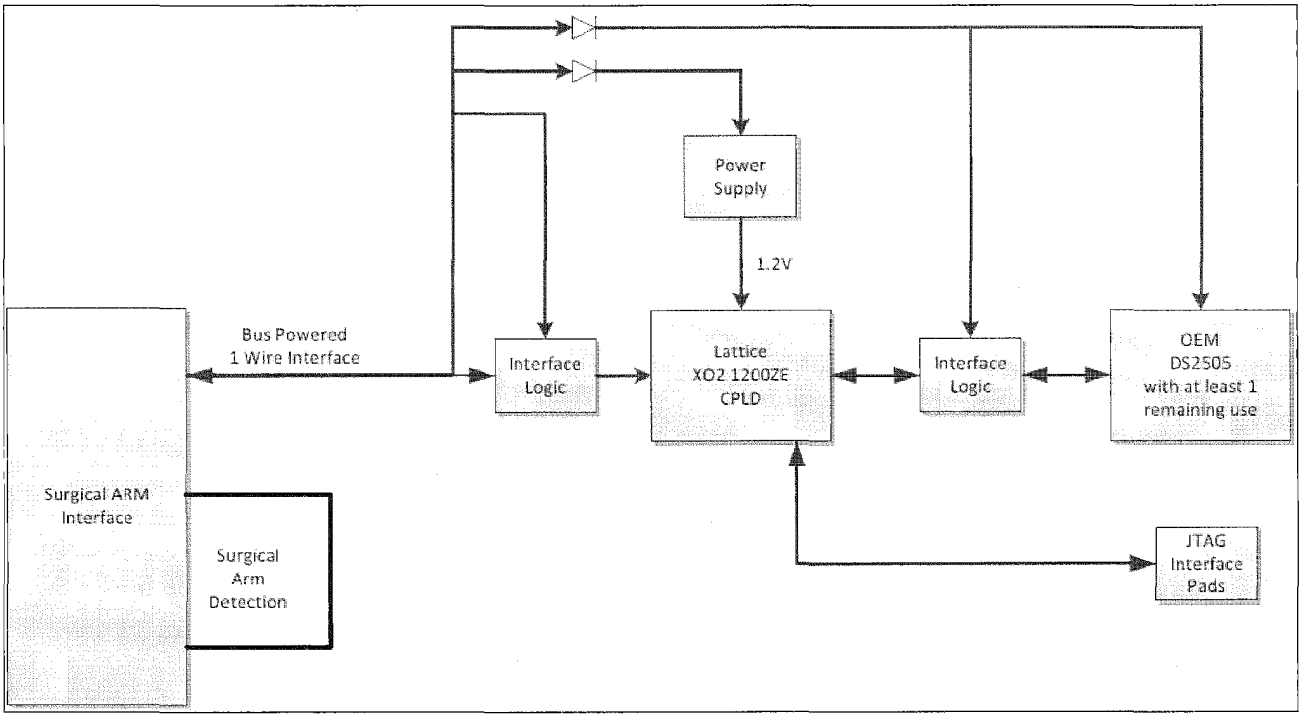

Figure 10

software_communicate_with_host_system

The Re-manufactured device shall communicate and respond to the host system as in the same manner as the OEM device. Note: The interceptor PCB assembly, Rebotix P/N PR1110-002, shall masks and substitute the data to and from the DS2505 to the host with the data stored in the Interceptor flash memory.

software_resettable_counter

The Re-manufactured device shall provide a factory resettable counter.

software_host_system_displayable_information

The Re-manufactured device shall display the same information to the host system as the OEM wrist with the exception of the resettable counter. Displayed information includes:

1) Device Lot Number

2) Device Description

3) Device Number of Uses Remaining ("Uses Left").

Refer to Rebotix Document PR3005 for the Software Requirements Specification for the device.

[redacted]

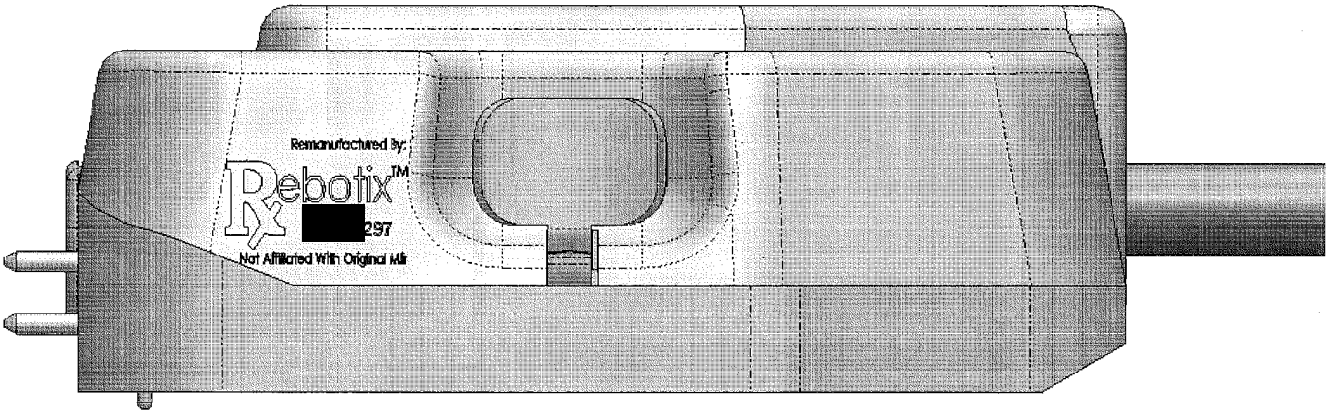

Figure 11

device labeling_laser_etching

The housing of the Device shall be laser etched with the Rebotix Company Logo with Laser marking Ink, CerMark P/N LMC-6044P Black.

device labeling_extended_uses

All labeling, text, numbers and symbols, on the housing of the device shall be legible after 11 additional life uses, including scrubbing, flushing, ultrasonic cleaning, autoclaving, routine handling and clinical use.

device_labeling_serial_number

The serial number of the device must match the serial number displayed on the Host System once connected.

packaging_labels

The package labels shall meet the [redacted] requirements for the market where the device is distributed.

device_IFU

The Instructions for use (IFU) shall be included with device. The IFU shall be translated into the required languages for sale outside the United States. [redacted]

11 PACKAGING / SHIPPING REQUIREMENTS

device_final_packaging

The Device will be packaged individually in a cardboard box composed of the following:
Box Insert, Rebotix P/N PR1141-002.
Box, Rebotix P/N PR1140-002
Each box shall contain an Instructions For Use

device_packaging_tip_protector

The Device will be packaged with a tip protector, Rebotix PR1145-002, placed on the tool end of the device to protect during shipping and handling of the device. Note: The tip protector is to be removed before cleaning and sterilization.

ship_container

The Final Product Packaging Configuration for the Device shall meet the product's finished device release requirements after being subjected to Simulated Transportation Conditioning per ISTA 6 – FEDEX-A- FedEx Procedures for Testing Packaged Products Weighing Up to 150 lbs.

12 REQUIRED ACCESSORIES

This section describes additional components required for safe operation of the EndoWrist.

Cannula, Intuitive P/N's 420254, 420002
Instrument Arm Drape Intuitive P/N 420015
Host System, daVinci S or Si

One of the following Bipolar Energy Activation Cables. Dependent upon ESU used.

Bipolar Energy Activation Cable, Valleylab, Intuitive P/N 371498

Bipolar Energy Activation Cable, Erbe, Intuitive P/N 371499

Bipolar Energy Activation Cable, CONMED, Intuitive P/N 371500

Bipolar Energy Activation Cable, Gyrus, Intuitive P/N 370369

Bipolar Energy Activation Cable, Megadyne, Intuitive P/N 371483

Joe Morrison

From: jschuenke@gmail.com on behalf of Jay Schuenke <jay@horizon-pd.com>
Sent: Thursday, October 09, 2014 1:42 PM
To: Joe Morrison
Subject: Re: FW: Emailing: RMPR1001 Rev BEndowristPlanFINAL (RB revisions)

Joe,

Looks good.

Thanks.

Jay Schuenke
Principle, Director of Design and Development
Horizon Product Development
Ph. 727-871-8011
Fax 866-629-5176

On Thu, Oct 9, 2014 at 1:38 PM, Joe Morrison <joemorrison@rebotix.net> wrote:
Jay just realized you weren't included in this. Please review and advise if you are good with redlines.

Only additional item will be to remove Casica Engineering as part of RM team.

Please let me know.

Thanks

-----Original Message-----
From: Ryan Burke [mailto:rburke@ajwtech.com]
Sent: Friday, October 03, 2014 6:11 PM
To: Joe Morrison
Cc: Jon Ward
Subject: Emailing: RMPR1001 Rev BEndowristPlanFINAL (RB revisions)

Joe,

This is my latest revision of the RM Plan. It should be ready for approval at the next rev.

-Ryan

Your message is ready to be sent with the following file or link attachments:

RMPR1001 Rev BEndowristPlanFINAL (RB revisions)

Note: To protect against computer viruses, e-mail programs may prevent sending or receiving certain types of file attachments. Check your e-mail security settings to determine how attachments are handled.